From: Michael Peters [mpeters@acr.org]
Sent: Friday, November 07, 2008 3:59 PM
To: Rulemaking Comments
Cc: Gloria Romanelli; Michael Peters
Subject: ACR Comments - RIN 3150-AI26
Attachments: nrc_proposed-rule_35-30_perm-brachytherapy_acrdraftcomments_11-2008.pdf

Attached are comments from the American College of Radiology (ACR) addressing the proposed rule on medical events in permanent brachytherapy (RIN 3150-AI26). Thank you.

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November 7, 2008

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

Subject: RIN 3150-AI26; Medical Use of Byproduct Material-Amendments/Medical Event Definitions; Proposed Rule

Dear NRC Rulemakings and Adjudications Staff:

The American College of Radiology (ACR) appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission's (NRC) proposed rule revising the criteria for medical events in permanent brachytherapy enumerated in 10 CFR 35.40 and 35.3045. The ACR is a professional organization serving more than 32,000 radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists, who use radiation and radioactive material for the benefit of their patients.

As a general comment, we would note that the topic addressed in this rulemaking was discussed at length by the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) in various meetings, reports, and recommendations. Most recently, the ACMUI approved a report in October 2008 prepared by its Permanent Brachytherapy Subcommittee (PBSC) that addressed this proposed rule and contained, in part, the concerns described below. We urge that the deliberations and recommendations of the ACMUI be duly reflected in the language and implementation of the final rule.

10 CFR 35.3045(a) – Failure to Provide WD

The ACR opposes the proposed language in 35.3045(a) that would make any instance where a written directive (WD) is required but not provided a medical event. A change of this nature would be a significant deviation from the current rule criteria and appears to contradict the ACMUI Medical Event Subcommittee's original recommendation in April 2005 and the PBSC's report in October 2008 that medical event rule criteria for modalities other than permanent brachytherapy should not be altered during this effort. Additionally, the technical basis supporting the proposed rule does not provide a rationale for opposing the ACMUI's recommendations in this regard.

The ACR understands the NRC's desire to be alerted to situations in which WDs were required but not provided. We do not agree, however, that medical event classification is an appropriate mechanism to capture those instances in which there was a clerical error that had not adversely affected patient care. The notification requirements that are triggered once a medical event is discovered (in accordance with 35.3045) can cause unnecessary worry and concern for patients/public and create an undue administrative and medico-legal burden on the part of the physicians and their institutions. This burden should not have to be shouldered by the users/licensees in situations in which the best medical care was provided to patients notwithstanding a clerical oversight.

Moreover, if the NRC chooses to incorporate this language, which is neither specific to permanent brachytherapy nor consistent with the advisory committee's recommendations upon which this proposed rule is based, it should be handled via a different rulemaking and supported by a relevant technical basis. However, the ACR strongly recommends that the NRC work directly with the ACMUI to identify an

alternative method of capturing rule violation data when the violations are not elevated to the level of medical events.

10 CFR 35.3045(a)(2) – Seed Migration

The ACR supports the NRC's language in 35.3045(a)(2) that explicitly excludes seed migration from triggering a medical event. Seed migration is largely outside of the control of the licensee and is not necessarily indicative of a major error or misadministration.

10 CFR 35.3045(a)(2)(i), (ii), (iii) and (iv) – "Preimplantation" WD

The ACR recommends that the undefined term "preimplantation" be removed from the proposed language of 35.3045(a)(2)(i), (ii), (iii) and (iv), and 35.3045(a)(3). This new terminology would unintentionally limit physicians' practice of medicine in the planning and administration of permanent brachytherapy. Given the nature of permanent brachytherapy and the real time, intraoperative decision-making involved, physicians must have flexibility to modify the total source strength administered during the procedure if, in their professional judgment, a change would result in better care for their patients than the total source strength estimated during previous planning and development of the "preimplantation" WD. The care of the patient is, by far, first and foremost among priorities, and the proposed rule must be fine-tuned under the direct guidance of the ACMUI to not infringe upon the fundamental practice of medicine by altering the parameters by which physicians plan and implement permanent brachytherapy procedures.

10 CDR 35.3045(a)(2)(ii), (iii), and (iv) – Treatment Site

The boundaries of the treatment site are not absolutely defined in permanent brachytherapy procedures, and the language in 35.3045(a)(2)(ii), (iii), and (iv) should be more flexible to allow for physician discretion and intended variance while focusing on capturing only major errors and misadministrations. The ACR recommends that the NRC work closely with members of the ACMUI to best address this, and other outstanding concerns, in the final rule.

As always, the ACR welcomes the opportunity for continued dialogue with the NRC on areas of mutual interest. Should you have any questions on the comments addressed herein, or if we can otherwise be of assistance, please do not hesitate to contact Gloria Romanelli, ACR Senior Director, Legislative and Regulatory Relations, or Michael Peters, ACR Assistant Director, Regulatory and Legislative Portfolio, at 202-223-1670.

Sincerely,

James H. Thrall, MD, FACR
Chair, Board of Chancellors
American College of Radiology

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